

### **REMARKS**

Claims 1-62 are pending, with claims 8-35 and 43-62 having been withdrawn from further consideration. By the present communication, no claims have been added, claims 6 and 40 have been canceled without prejudice or disclaimer, and claims 1, 3-5, 7, and 36-39 have been amended to define Applicant's invention with greater particularity. Support for the amended claim language may be found throughout the specification as filed. Accordingly, upon entry of this communication, claims 1-5, 7, 36-39, 41, and 42 will be pending.

#### **Objections to the Specification**

Applicant respectfully traverses the objection to the specification as allegedly failing to comply with the requirements of 37 C.F.R. §§1.821 through 1.825. It is respectfully submitted that the amendments set forth above remedy the absence of the appropriate numbers and direct insertion of the corresponding Sequence Listing into the specification. The Sequence Listing shows sequences that were present in the subject application as filed and, therefore, does not add new matter. The sequence listing in computer readable format as well as the appropriate statement as required by 37 C.F.R. § 1.822 to 1.824 are attached herewith. Accordingly, withdrawal of the objection is respectfully requested.

Applicant respectfully traverses the objection to the specification as allegedly failing to provide proper antecedent basis for the claimed subject matter. Specifically, the Office Action alleges that the specification does not have antecedent basis for the term "abnormal cell" cited in the claims. Without acquiescing to the reason of the Office, and in order to further prosecution of the application, Applicant has amended claims 1 and 36 to recite that the abnormal cells are cancer cells expressing  $\alpha_2\beta_1$ . Support for the amended claim language may be found, among others at paragraphs [0021], [0022], and [0024] of the published application. Applicant respectfully submits that at least the above-identified passages of the specification as filed provide sufficient antecedent basis for the term "abnormal cell." Accordingly, withdrawal of the objection is respectfully requested.

**Rejections under 35 U.S.C. §112, Second Paragraph**

Applicants respectfully traverse the rejection of claims 1-7 and 36-42 under 35 U.S.C. §112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office Action alleges that the metes and bounds of the cited abnormal cells are not defined. Applicant has canceled claims 6 and 40, rendering the rejection moot as to those claims. Without acquiescing to the reason of the Office, and in order to further prosecution of the application, Applicant has amended claims 1 and 36 to recite that the abnormal cells are cancer cells expressing  $\alpha_2\beta_1$ . Support for the amended claim language may be found, among others at paragraphs [0021], [0022], and [0024] of the published application. Applicant respectfully submits that as amended, the metes and bounds of the allegedly indefinite term of claims 1 and 36 are defined. Accordingly, withdrawal of the objection is respectfully requested.

**Rejections under 35 U.S.C. §112, First Paragraph**

Applicant respectfully traverses the rejection of claims 1-7 and 36-42 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office Action alleges that the specification does not provide a written description for using a modified echovirus or combination of the echovirus with modified forms thereof to treat an abnormal cell. Applicant has canceled claims 6 and 40, rendering the rejection moot as to those claims. Without acquiescing to the reason of the Office, and in order to further prosecution of the application, Applicant has amended claims 1, 3, 7, 36, and 37 to remove modified echoviruses and combinations of echoviruses and modified forms thereof. In addition, Applicant has amended claims 5 and 39 to recite that the echovirus has been modified to express the peptide motif RGD on its viral capsid surface. Support for the amended claim language may be found, among others, at page 18, lines 16-24, of the specification as filed, which discloses,

a virus maybe modified using site-directed mutagenesis so that the peptide motif "RGD" is expressed on the viral capsid surface. The RGD motif is recognised by

$\alpha_v$  integrin heterodimers and this capsid modification may for instance allow the virus to bind the integrin  $\alpha_2\beta_1$ , a cell adhesion molecule which has been shown to be upregulated on melanoma lesions (Natalia P. G; 1997) as has  $\alpha_2\beta_1$ , potentially leading to enhanced uptake of the virus by the target cell.

Accordingly, Applicant respectfully submits that the specification sufficiently describes the claimed subject matter, and requests withdrawal of the rejection.

### **Rejections under 35 U.S.C. §102**

Applicants respectfully traverse the rejection of claims 1, 3, 36, and 37 under 35 U.S.C. §102(b) as allegedly being anticipated by Ferdat, et al (Eksp Onkol 1989, Vol. 11, No. 5, pp. 43-48; hereinafter, "Ferdat"). To anticipate, a single reference must inherently or expressly teach each and every element of claimed invention. *In re Spada*, 15 USPQ2d 1655 (Fed Cir. 1990); and *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP § 2131.

The Office Action alleges that Ferdat discloses "a method for treating tumor using echovirus serotype 7 (echo-7) in mice. The treatment nevertheless causes tumor regression (see abstract). Because the method taught by Ferdat et al. contains the same active steps to the claimed method, claims 1, 3, 36-37 are anticipated by Ferdat et al". As the Examiner will note, the relevant independent claims of the instant application (*e.g.*, claim 1) recite that the virus is "an echovirus, which recognizes  $\alpha_2\beta_1$  for infectivity of the cells...." Applicant respectfully submits that EV-7 (*i.e.*, echo virus serotype 7 or echo-7) in fact does not recognize  $\alpha_2\beta_1$  for infectivity of the cells, but rather, that EV-7 infection instead involves interaction of EV-7 with the complement regulatory protein, decay accelerating factor ("DAF").

Applicant respectfully directs the Examiner's attention to paragraph [0125] of the published application, which states, "[t]o determine the relative expression levels of selected enteroviral cell surface receptors used by enteroviruses cytometric analyses was performed. The selected group of receptors consisted of ICAM-1 employed by CAV21; *DAF employed by EV-7*, ..." (emphasis added). Accordingly, since Ferdat fails to disclose each and every element of claimed invention, Applicant submits that Ferdat fails to anticipate the amended claims.

In addition, Ferdat states that the observed “inhibitor effect on the growth of MX-17 tumor” is apparent “without the signs of viral oncolysis” (see abstract). In contrast, the claims of the instant application require that “at least one of the cells are killed by the virus” (*e.g.*, claim 1), or “thereby causing lysis of at least one of the cells...” (*e.g.*, claim 36). Applicant respectfully submits that a reasonable interpretation of the Ferdat abstract is that no cells would be “killed” or “lysed” by the procedure described in Ferdat, as the reported inhibitory effect on the tumors is said to occur “without the signs of viral oncolysis.” Accordingly, since Ferdat fails to disclose each and every element of claimed invention, Applicant submits that Ferdat fails to anticipate the amended claims.

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Darren R. Shafren  
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**Conclusion**

The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

The Commissioner is hereby authorized to charge \$230.00 as payment for the Petition for Two-Month Extension of Time fee to Deposit Account No. 07-1896. Additionally, the Commissioner is hereby authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment to Deposit Account No. 07-1896, referencing the above-identified attorney docket number.

Respectfully submitted,

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